

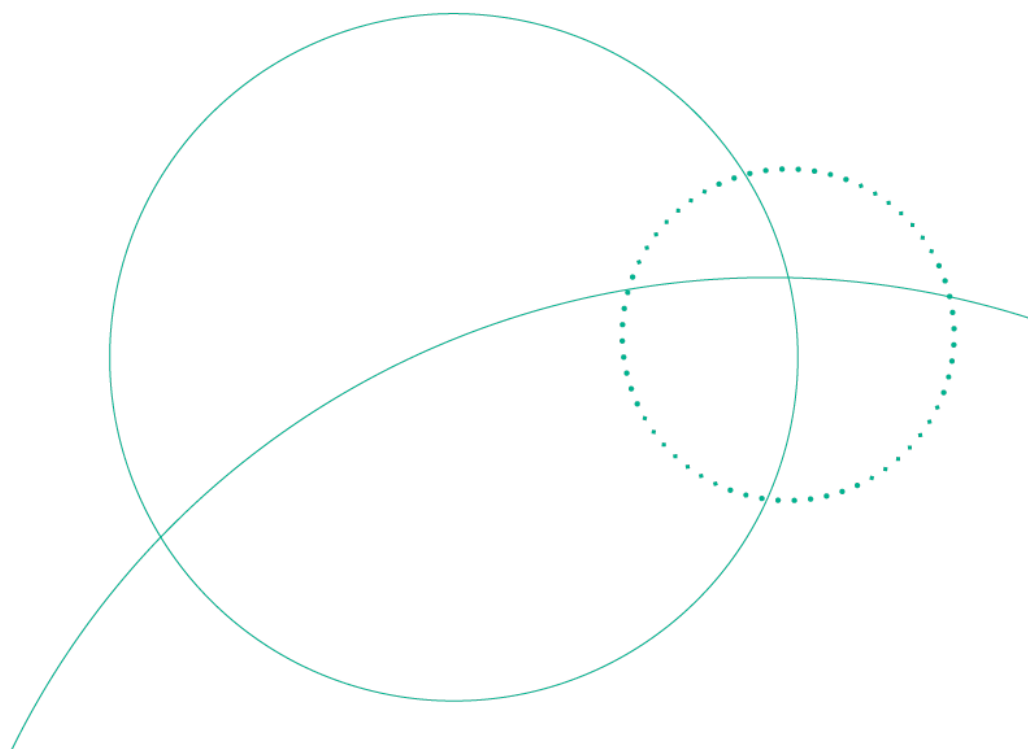
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 4

GreenNet LN
(Shobikaa Impex Private Limited)

P-00320

Safety Assessment



Contents

1 Risk assessment summary 3

1.1 Introduction 3

1.2 Active ingredient statement..... 3

1.3 Assessment 3

 1.3.1 Product Specific Acute Toxicity Data.....3

 1.3.2 Toxicity Information on the Active Ingredient3

 1.3.3 Comparison of the GreenNet LN Specifications vs. GRA Values4

1.4 Discussion and conclusion 4

2 References 5

1 Risk assessment summary

1.1 Introduction

The applicant, Shobikaa Impex Private Limited, (India) submitted to the World Health Organization (WHO) Prequalification Unit Vector Control Product Assessment Team (PQT-VCP) a dossier containing supporting data on the product GreenNet LN and requested WHO assessment for the purpose of prequalification. GreenNet LN is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric is made from polyester filaments which is coated with Deltamethrin (CAS No. 52918-63-5).

1.2 Active ingredient statement

Deltamethrin (1R,3R)-R-cyano (3-phenoxyphenyl) methyl 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate (CAS No. 52918-63-5) is a broad-spectrum pyrethroid insecticide that is registered for direct application to a wide variety of food/feed crops, for use on stored grains, for use in food/feed handling establishments and as a wide-area mosquito adulticide.

1.3 Assessment

1.3.1 Product Specific Acute Toxicity Data

Acute 6-pack toxicity data for the proposed ITN was submitted and a summary of these studies is provided in Table 1. The test material in all acute studies was Deltamethrin extracted from cut filaments of GreenNet LN with acetone and reconstituted in corn oil to the desired dose level or concentration. All acute studies were conducted at IIBAT (International Institute of Biotechnology and Toxicology, India) in compliance with Good Laboratory Practices (GLP) and OECD guidelines.

Using the Globally Harmonized System of Classification and Labelling of Chemicals (GHS, 2017), GreenNet LN has low acute oral, dermal and inhalation toxicity (Category 5), is not an eye or skin irritant, and is not a skin sensitizer.

Table 1. Acute toxicity of GreenNet LN				
Route of exposure	Species	Toxicity	GHS category	Reference
Oral	Rat	LD ₅₀ = >2000 mg/kg bw	5	IIBAT, 2020a
Dermal	Rat	LD ₅₀ = >2000 mg/kg bw	5	IIBAT, 2020b
Inhalation (nose only)	Rat	LC ₅₀ = > 5.06 mg/L/4 hrs	5	IIBAT, 2020c
Dermal irritation	Rabbit	Non-irritant	Not classified	IIBAT, 2020d
Eye irritation	Rabbit	Non-irritant	Not classified	IIBAT, 2020e
Dermal sensitization	Guinea pigs	Non-sensitizer	Not classified	IIBAT, 2022

1.3.2 Toxicity Information on the Active Ingredient

The toxicology database for Deltamethrin is adequate to address the health hazard and to assess the risks associated with the proposed uses of GreenNet LN as an ITN.

The human health risk assessment, including hazard, exposure, and risk characterization for Deltamethrin is presented in the “*Generic Risk Assessment – Human Health – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets*” published by WHO (2021). The generic risk assessment (GRA) published by WHO is intended to be used as an example of the implementation of the “*Generic Risk Assessment Model for Insecticide-Treated Nets, 2nd edition*” (GRAM)(WHO, 2018) and points of reference for the assessment of new products which are formulated with this active ingredient.

1.3.3 Comparison of the GreenNet LN Specifications vs. GRA Values

The proposed specifications for Deltamethrin in the product GreenNet LN are less than the characteristic values in the Deltamethrin GRA. (WHO, 2012)

Table 2. Comparison of the GreenNet LN characteristics vs. GRA selected representative values		
Attribute	GreenNet LN	Deltamethrin GRA
Concentration by weight	1.4 g/kg net	3.0 g/kg net
Net size	13.08 g/m ²	15 g/m ²
Concentration by net area	56 mg/m ²	120 mg/m ²
Wash resistance index	97.62% ^a	90%

^a IIBAT, 2020f

1.4 Discussion and conclusion

The risk assessment was conducted according to the guidance provided in the most recent “*Generic Risk Assessment Model for Insecticide-Treated Nets, 2nd edition*” (GRAM)(WHO, 2018). In support of new product applications or change applications submitted to the WHO Prequalification Unit – Vector Control Product Assessment Team, applicants may include reference to the GRAs as part of the product dossier.

Based on the proposed product characteristics and the use pattern, it was determined that the risk ratios for GreenNet LN are acceptable (i.e., less than 1) for all population subgroups (adults, children, toddler, infants and newborn), for all exposure scenarios (sleeping under the net, washing the net, sleeping under and washing the net) and the exposure routes (oral, dermal and inhalation) similar to those obtained for Deltamethrin the respective GRA (WHO, 2021).

The product characteristic values for GreenNet LN which differ from the representative values all result in a decrease in the calculated risk ratios meaning that the product does not pose any additional risk to human health beyond the assessment provide in the GRA (WHO, 2021).

Therefore, it can be concluded that the ITN proposed product GreenNet LN can be used safely for its intended purpose.

Assessment of the submitted information supports the prequalification of the product GreenNet LN.

2 References

GHS, 2017. Globally Harmonized System of Classification and Labeling of Chemicals – Seventh revised edition, United Nations, New York, and Geneva. Available at:

https://unece.org/DAM/trans/danger/publi/ghs/ghs_rev07/English/ST_SG_AC10_30_Rev7e.pdf

IIBAT (International Institute of Biotechnology and Toxicology), 2020a. GreenNet – Deltamethrin 1.4 g/kg coated onto polyester filaments of Long-Lasting Insecticidal Net: Acute oral toxicity study in rats. Study No. 20017. Dated 17/09/2020.

IIBAT, 2020b. GreenNet – Deltamethrin 1.4 g/kg coated onto polyester filaments of Long-Lasting Insecticidal Net; Acute Dermal Toxicity Study in Wistar Rats. Study No. 20018. Dated 17/09/2020.

IIBAT, 2020c. GreenNet - Deltamethrin 1.4 g/kg coated onto polyester filaments Long Lasting Insecticidal Net: Acute inhalation toxicity study in Wistar rats. Study No. 20019. Dated 17/09/2020.

IIBAT, 2020d. GreenNet – Deltamethrin 1.4 g/kg coated onto polyester filaments of Long-Lasting Insecticidal Net: Acute dermal irritation/corrosion study in New Zealand white rabbits. Study No. 20120. Dated 17/09/2020.

IIBAT, 2020e. Deltamethrin 1.4 g/kg coated onto polyester filaments of Long-Lasting Insecticidal Net: Acute eye irritation/corrosion study in New Zealand rabbits. Study No. 20121. Dated 17/09/2020.

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